REMARKS

Claims 12-24 remain pending in this application. Claims 12 and 19 have been amended as described below. No new matter has been added.

The reply after final action is considered to be the submission to accompany the Request for Continued Examination. Applicants note that the Examiner has acknowledged receipt of the claim for foreign priority and associated priority documents, and has considered the documents cited in the IDS filed May 16, 2008.

Claims 12-24 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for several reasons that will be addressed below.

A. Claim 12 was rejected because it is allegedly unclear whether the claimed apparatus requires a human, or at least a human inhaling on the apparatus to meet the claim limitations. A human user is not a component of the claimed device, but the reference to "inhalation by a user" merely sets forth the manner in which the structure of the air inlet flow path must function as an element of the claimed device. To more clearly point out that the air inlet flow path must be configured to accomplish the recited functions as a result of the inhalation by a user, claim 12 has been amended to point out that the air inlet flow path for introducing outside air and for injecting outside air does so "as a result of inhalation by a user." Accordingly, this rejection should be withdrawn.

B. Claim 19 has been rejected because the term "cake-like" allegedly renders the claim indefinite. While it is recognized that the use of the term "like" may introduce some lack of clarity in some situations, the present specification contains a description (see, e.g., page 32, line 23 to page 33, line 11) of the composition and how it may resemble a cake. Although the term "cake-like" is not considered to be indefinite under

the circumstances of this case, the term has been deleted from claim 19 to render this rejection moot.

C. Claim 23 has been rejected as confusing because it is allegedly unclear if the air-generated impact is being applied or not. Claim 23 is directed to an inhalation device that is arranged and configured in such a manner as to perform certain recited functions upon inhalation by the user. The claims do not require the step of an air-generated impact, but do recite that the device will achieve certain functions upon inhalation by a user. Accordingly, this claim is not indefinite and this rejection should be withdrawn.

Claims 12-18 and 20-24 have been rejected as being unpatentable over Lerk et al. (U.S. Patent No. 5,301,666) in view of Gabrio et al. (U.S. Patent No. 6,615,826). According to the Office, Lerk et al. teaches the features recited in these claims except for the specific teaching that the auxiliary air flowing out from the auxiliary flow path does not disturb the air flow of the inhalation flow path. Gabrio et al. is cited for the teachings that an air sheath flowing out of the auxiliary flow path (via 66) would not disturb the air flow of the inhalation flow path, and that additional dividers with decreasing aperture sizes may be provided at spaced intervals.

Claim 12 has been amended to recite that the pharmaceutical composition is contained in the chamber and that it is in a non-powder, freeze-dried form which is pulverized into fine particles by an air-generated impact. The claimed device contains the recited pharmaceutical composition which is in a form different from either Lerk et al. or Gabrio et al. For this reason alone, neither Lerk et al. nor Gabrio et al., alone or in

combination, teach an element of the claimed device and could not establish a prima facie case of obviousness of the device as claimed.

Lerk et al. teaches a powder inhaler which includes a dosage chamber filled with active substance in particulate form (col. 3, lines 1-8 and col. 5, line 42). Agglomeration of the active substance in the dosage reservoir is prevented by configuration of the inhaler (col. 3, lines 9-13), whereas centrifugal forces and impacts of the particles against each other and against the wall divide up any remaining agglomerates. The pharmaceutical composition of the claimed invention is in a non-powder freeze-dried form which is pulverized into fine particles by an air-generated impact. The inhaled air in the Lerk et al. device serves only to entrain the drug particles through the device (col. 4, lines 19-34), and not to pulverize the composition into fine particles.

Gabrio et al. is even further removed from the claimed device since it does not relate to a powder inhalation device, but to a spray inhaler in which an aerosol stream comprising liquefied propellant and medicament from a dispensing canister may be administered by a mouthpiece or nasal adapter (see, col. 1, lines 13-18; col. 2, lines 32-34). The Gabrio et al. device does not contain a pharmaceutical composition in non-powder, freeze-dried form which is pulverized into fine particles by an air-generated impact. The inhaled air in the Gabrio et al. device also does not serve to pulverize a non-powder, freeze-dried composition into fine particles, but to entrain the aerosol spray (col. 4, lines 24-26). Accordingly, since neither Lerk et al. nor Gabrio et al. teach all the features of the claimed invention, this rejection should be withdrawn.

Claim 19 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Lerk et al. in view of Gabrio et al. and further in view of Horlin (2001/0020472).

Although the Office argues that Lerk et al. and Gabrio et al. teach all the limitations of claim 19 except for the unsealing member for releasing the sealed condition of a vessel, applicants disagree. Claim 19 is dependent on claim 12 and necessarily includes the pharmaceutical composition in non-powder, freeze-dried form which is pulverized into fine particles by an air generated impact. For the reasons discussed above, none of the applied patent documents teach this element of the claimed inhalation device.

Horlin, like Lerk et al., uses a chamber (capsule) filled with particles in which the inhaled air serves to entrain the existing powder and draw it through the device (paragraph 0046, at page 3). Horlin does not use a freeze-dried composition and the powder inhaler is not arranged such that an impact of air will pulverize the freeze-dried composition into fine particles. Accordingly, this rejection should be withdrawn.

Prompt and favorable reconsideration of this application is respectfully requested.

If there is any fee due in connection with the filing of this Reply, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: Charles E Van Horn

Charles E. Van Horn
Reg. No. 40,266
Tel: 202 408-4072